510(k) Summary

AUG 16 2012

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. Name and Address of Applicant

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B. Contact Person

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Regulatory Affairs Consultant
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C. Date Prepared

July 13, 2012

D. Device Name

Trade Name:	Minimally Invasive Surgical (MIS) Decompression System
Common Name:	Arthroscope
Classification Name:	Arthroscope

E. Device Classification

Classification:	21 CFR §888.1100
Product Code:	HRX
Device Class:	Class II

F. Predicate Device

The modified Minimally Invasive Surgical (MIS) Decompression System is substantially equivalent to the Spine View SpineVu Endoscopic Spine System (SESS) (K113362 and K08151) and predicate cutting instruments offered as part of the Richard Wolf Medical Instruments Corp. Minimally Invasive Spinal Surgery Set (K994363) and several Class I orthopedic manual surgical instruments, including the Joimax EndoReamer and EndoChisel Assembly.

G. Device Description

The Minimally Invasive Surgical (MIS) Decompression System is a collection of arthroscopic surgical accessories provided sterile (irradiated) and intended for single-use only. As a group, the accessories are provided to facilitate delivery of an endoscope and other instruments to the targeted treatment site. The addition of a new accessory, the enCise Bone Cutter, as an additional surgical tool to facilitate removal of soft and hard (bone) tissue during interventional spinal procedures. The new component will be offered in two configurations: one compatible with flexible endoscopes, and the second compatible with rigid endoscopes. Two additional enVue Cannula models are also being introduced for compatibility with rigid endoscopes: Long and Standard Jaw. Introduction of the new enCise Bone Cutter and additional configurations of the already cleared enVue Cannula do not affect the intended use or alter the fundamental scientific technology of the system.

The additional accessories being proposed in the modified MIS Decompression System are listed below:

- **enCise Bone Cutter:** a tubular sheath with a mechanical "chisel" tip feature designed to cut soft and hard (cartilaginous, bone) tissue during spinal procedures. The enCise Bone Cutter is offered in two configurations (one compatible with flexible endoscopes, and the second compatible with rigid endoscopes).
- **enVue Cannula, Standard and Long Jaw:** configurations for use with rigid endoscopes. The working end of the accessories is identical to the previously cleared enVue Cannulas. The only difference is in the handle, which is modified to accommodate rigid endoscopes (up to 5.9 mm OD; 205 mm working length).

H. Intended Use

The Spine View Minimally Invasive Surgical (MIS) Decompression System is indicated for use to facilitate access and visualization in the surgical area of the cervical, thoracic, or lumbar spine and is accessorized with surgical tools for interventional spinal procedures such as discectomy, nucleotomy and foraminotomy.

I. Technological Comparison

The Spine View Minimally Invasive Surgical (MIS) Decompression System has similar features as compared to the predicate devices as shown in the tables below:

enCise Bone Cutter

	Predicate	Predicate	Subject
Company, K#	**Richard Wolf Minimally Invasive Spinal Surgery Set, K994363**	**Joimax, Inc., TESSYS Surgical Instruments, N/A – Class I Exempt**	**Spine View MIS Decompression System, K121548**
Device Name	**Punches**	**EndoReamer, EndoChisel**	**enCise Bone Cutter**
Intended Use	endoscopically controlled dissection, exploration, and manipulation of tissue through natural or surgically created passages to grasp, manipulate, and cut, as well as for the dissection and biopsy of tissue, organs, or foreign bodies. punching and removal of tissue through natural or surgically created passages.	The Joimax TESSYS Spinal Stenosis System is a set of endoscopic instruments that facilitate removal of osseous/bony material under direct endoscopic imaging. The EndoReamer and EndoChisel instruments are intended to remove osteophytes and calcifying tissues, including coarse stenosis fragments.	enCise Bone Cutter is intended to facilitate removal of remove osteophytes and calcifying tissues under direct endoscopic visualization.
Product Code	HRX, Class II	LXH, Class I – 510(k) Exempt	HRX, Class II
Design	The punch-featured instruments are designed with a sliding jaw, which is forced into the material to be cut by depressing the mechanical actuator in the handle.	The chisel-featured instruments are designed with a characteristically shaped cutting edge, which are forced into the material to be cut by use of a surgical mallet or manual manipulation	Same
Dimensions	2.5 – 4.0 mm OD, WL 290 - 360 mm (≈2.5-4.0 mm cutting element tip width)	EndoReamer: Single Working Channel for endoscope and endoscopic instruments 3.0-7.5 mm ID; 4.0-8.5 mm OD; WL 210 mm (4.0 – 8.5mm circular serrated tip diameter) EndoChisel: 2.6 or 3.0 mm OD, WL 370 mm (≈2.6 or 3.0 mm chisel tip width)	Single Working Channel for endoscope and endoscopic instruments 6.12 mm ID, 7.16 mm OD, 196 &198 mm WL (3.76 mm chisel tip width)
Patient Contact Materials	Stainless Steel	Same	Same
Target Anatomy	Intervertebral procedures	Same	Same
Supplied Sterile?	No	No	Yes
Single Use?	No	No	Yes

enVue Cannula

	Predicate	Subject
Company, K#	**Spine View, MIS Decompression System K113362**	**Spine View, MIS Decompression System K121548**
Device Name	**enVue Cannula**	**enVue Cannula**
Intended Use	1. Access cannula with working channel for endoscope, endoscopic instruments, and irrigation and drainage 2. Distal feature for retracting tissue away from end of cannula	1. Same 2. Same
Product Code	HRX, Class II	Same
Design	Articulating Top Jaw can be mechanically actuated to retract tissue away from end of cannula Distal tip: Articulating jaw (Nylon) for tissue retraction (Standard and Long jaw configurations)	Same
Dimensions	1. OD: 0.282" 2. Working Length: 7.5" 3. Length, Tissue Retraction Feature 0.394" 4. OD, Tissue Retraction Feature: 0.354 " 5. Single Working Channel 0.240" for enVue Sheath (for endoscopic instruments and endoscope [2 mm OD]	1. Same 2. Same 3. Same 4. Same 5. Single Working Channel 0.240" for endoscopic instruments and endoscope [5.9 mm OD]
Patient Contact Materials	Stainless Steel, Nylon-12	Same
Target Anatomy	Intervertebral procedures	Same
Supplied Sterile?	Yes	Same
Single Use?	Yes	Same

The technological characteristics and principals of operation of the modified Spine View Minimally Invasive Surgical (MIS) Decompression System are substantially equivalent to the named predicate devices. .

J. Non-Clinical Performance Data

The following non-clinical testing was conducted to support a determination of substantial equivalence to the predicate device.

• Device to Device Compatibility Testing	• Jaw Cycle Integrity Testing
• Joint Integrity Testing	• Jaw Activation Testing
• Tip Rotation	• Biocompatibility Testing
• Tip Robustness	• Design Validation Testing
• Handle/Joint Integrity	• Packaging Testing
• Jaw & Trigger Force Testing	• Sterility Testing

The above testing confirmed that the Spine View Minimally Invasive Surgical (MIS) Decompression System performs according to the stated intended use. All data fell well within product specifications and external standard requirements. Results of non-clinical testing demonstrated that the Spine View Minimally Invasive Surgical (MIS) Decompression System is substantially equivalent to the predicate devices for its intended use.

K. Conclusions

The Spine View Minimally Invasive Surgical (MIS) Decompression System has been carefully compared to legally marketed devices with respect to intended use and technological characteristics. In addition, non-clinical testing was conducted to validate the performance of the device and ensure the modified Spine View Minimally Invasive Surgical (MIS) Decompression System functions as intended and meets design specifications. The comparison and non-clinical results demonstrate that the device is substantially equivalent to the predicate device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room --WO66-G609
Silver Spring, MD 20993-0002

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AUG 16 2012

Re: K121548
Trade/Device Name: Minimally Invasive Surgical (MIS) Decompression System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: July 15, 2012
Received: July 18, 2012

Dear Ms. DeGregorio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

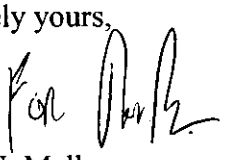
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K_____

Device Name: Minimally Invasive Surgical (MIS) Decompression System

Indications for Use:

The Spine View Minimally Invasive Surgical (MIS) Decompression System is indicated for use to facilitate access and visualization in the surgical area of the cervical, thoracic, or lumbar spine and is accessorized with surgical tools for interventional spinal procedures such as discectomy, nucleotomy and foraminotomy.

Prescription Use ___X___ **Or** **Over-The-Counter Use** _____

(per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121548